SUPPORT FOR THE AMENDMENTS

Claims 14 and 22 have been amended.

Claims 21 and 29 were previously canceled.

The amendment of Claim 14 is supported by the previously presented corresponding claim and the specification at page 6, lines 4-6. The amendment of Claim 22 is supported by the previously presented corresponding claim and the specification at page 5, lines 16-17, page 17, lines 3-23, and page 20, lines 10-16.

No new matter has been entered by the present amendment.

REMARKS

Claims 1-20, 22-28, and 30 are pending in the present application.

At the outset, Applicants wish to thank Examiner Soroush for the recognition that Claim 30 is free from the art of record. Reconsideration of the outstanding rejections is requested in view of the amendment herein and the following remarks.

The rejections of (a) Claims 14-17, 20, 22-25, and 28 under 35 U.S.C. §103(a) over Burgstiner in view of Moretti, Meisner, and Bryan; and (b) Claims 18 and 19 under 35 U.S.C. §103(a) over Burgstiner in view of Moretti, Meisner, and Bryan and further in view of Fisher et al and Ansel et al, are respectfully traversed.

The Examiner now appears to recognize that the claimed invention is not obvious in view of the combined disclosures of Moretti and Meisner, even when in view of Fisher et al and Ansel et al. However, the Examiner now cites Burgstiner. Burgstiner discloses and claims a composition containing many components (see, for example, the Abstract and Claim 10), including thymic-derived factors and enzymatic co-factors, wherein the thymic-derived factors can be thymus extract, thymus enzymatic polypeptide factors, thymosin, thymopoietin and thymic humoral factor and the enzymatic co-factors can be vitamins A, C, D, E, B-1, B-2, B-6, B-12, minerals, amino acids which can be arginine, cysteine, histidine, ornithine, isoleucine, leucine, threonine, tyrosine, valine, phenylalanine and methionine, and glandular factors which can be raw spleen, raw lymph, raw bone marrow and raw pituitary. Further, Burgstiner disclose that their composition is useful for the treatment of many disorders including inflammatory bowl disease, hepatosplenomegaly associated with inflammatory disease, rheumatoid arthritis, and connective tissue disease (see, for example, page 9, line 13

to page 10, line 7, page 11, lines 9 to page 12, line 16, and Claim 16).

The Examiner cites Moretti to allegedly show that oral or parenteral administration of ornithine to treat inflammatory bowel disease, heptao-splenomegaly associated with inflammatory disease, rheumatoid arthiritis, and connective disease. The Examiner alleges that it would be obvious to combine this disclosure with Meisner, who is asserted as teaching a composition to treat tissue degenerative inflammations and inflammatory diseases with valine. While Bryan is cited to alleged show that a method of administering at least one essential amino acid and that is it useful in treating an autoimmune disease inclusive of rheumatoid arthritis.

Burgstiner disclose formulation on pages 21-23 and in Example 1 that contain many ingredients. Further, in Example 3 of Burgstiner this composition is administered to a patient suffering from rheumatoid arthritis. However, Applicants direct the Examiner's attention to the fact that the method of the present invention requires administering to a subject in need of treatment of arthritis or depressing the progression of rheumatoid arthritis a composition *consisting essentially of* an effective amount of ornithine and at least one branched amino acid (see Claims 18 and 22). As set forth in MPEP §2111.03, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). None of Burgstiner, Moretti, Meisner, and Bryan disclose or suggest a composition *consisting essentially of* an effective amount of ornithine and at least one branched amino acid as presently claimed or the advantages flowing therefrom.

With respect to the beneficial effects flowing from the co-administration of ornitine and at least one branched amino acid, the Examiner is reminded of to Table 6 of Example 9

(below).

Table 6: Effect of Combined Ornithine and BCAA on CIA

Drug	Ratio of Individuals with Arthritis (%)	Arthritis Score
Control Group	100	3.2
Ornithine	30	0.8
BCAA	30	1.2
Combined Group	0	0

These results unequivocally show that the combined administration of ornithine and branched amino acids exemplified by L-isoleucine:L-leucine:L-valine at a ratio of 1:2:1.2 absolutely inhibited disease development, which could not be achieved with the individual administration of the active ingredients.

Fisher et al and Ansel et al are merely cited as disclosing food and drinks to which the active ingredients may be added. However, these references fail to compensate for the aforementioned deficiencies in the disclosures of Moretti and Meisner. As such, even when viewing the combined with the disclosures of Moretti and Meisner, the present invention would not be obvious.

Accordingly, Applicants request withdrawal of these grounds of rejection.

The objection to Claim 30 as being dependent upon a rejected base claim is respectfully traversed. For the reasons given above, Applicants submit that Claim 14, from which Claim 30 depends, is free from the art of record. As such, withdrawal of this ground of objection is requested.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

Stephen G. Baxter, Ph.D.
Registration No. 32,884

Vincent K. Shier, Ph.D.
Registration No. 50,552

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413-2220
(OSMMN 08/03)